

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
P08-508-509 Commun E	50100000102	10-15-09

COMMENTS:

ORIGINAL

DOES NOT CONTAIN CBI

ML-40237

OCT 14 2009

CONTAINS NO
CBI

Jane Bradd Andersen, Regulatory Affairs
DuPont Engineering Polymers
Chestnut Run Plaza
Building 702, Room 2009C
4417 Lancaster Pike
Wilmington, DE 19805

Re: PMN-08-508 and 509

Dear Ms. Andersen:

The Environmental Protection Agency ("EPA") has reviewed the submitted protocols for the 1) 90-day Toxicity Study (gavage) in mice, 2) Absorption, Distribution, Metabolism and Elimination (ADME) study in the Rat and Mouse, and 3) the Fish Early Life Stage study on the chemical substance, P08-509 described in the above-referenced consolidated premanufacture notice ("PMN"). These studies are required by EPA, under the authority of §5(e) of the Toxic Substances Control Act ("TSCA"), before you may exceed the production volume specified in the Consent Order governing this PMN substance.

EPA's comments and recommendations on the proposed protocols are designed to avoid potential problems so that the results of the study will be scientifically valid test data. Under no circumstance does approval of the test protocol mean pre-acceptance of test results.

EPA finds the protocols of the 90-day Toxicity Study in mice and the ADME study in rats and mice acceptable as submitted. No comments are offered.

For the Fish Early Life Stage study, we offer the following comments:

Based on the classification of PMN P08-0509 as an anionic surfactant, the OECD Difficult to Test Substances Guidance (e.g., low water solubility chemicals) document should be reviewed for how best to prepare this chemical for exposure in an aqueous environment:

<http://titania.sourceoecd.org/vl=1170542/cl=12/nw=1/rpsv/ij/oecdjournals/1607310x/v1n5/s21/p1>

Formation of a clear microdispersion or a milky macrodispersion is acceptable but tested concentrations should not exceed the maximum dispersibility limit.

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Specific Comments

- 1) The study report must state the purity of the test substance and a certificate of analysis provided to verify the accuracy and precision of the measurement technique. The Consent Order requires that the ammonium salt of the PMN substance (P-08-509) be tested.
- 2) The study report must provide an acceptable method of fry/alevin transfer from the embryo cups to the test chambers.
- 3) In section "H.", acceptability criteria must be provided if flow-rate in the exposure chambers drops below 10% of the 5 volumes per 24 hours turn-over rate.
- 4) The study report must provide the weights and lengths of each test organism in the exposure.
- 5) State which fish species will be used and the duration of the test.
- 6) State whether flow-through or static renewal conditions will be used. Likewise state whether the test concentrations will be measured or nominal. EPA emphasizes that the preference is for flow-through conditions and measured concentrations, especially because this PMN substance has been deemed a difficult to test substance.

Conclusion for the Fish Early Life Stage study protocols:

The submitted study protocols appear to parallel respective OPPTS guidelines. The general and specific comments provided above should be addressed.

I expect that the protocol review for the submitted Avian Reproduction Study will be finalized shortly.

If you have any questions or comments, please contact me at (202) 564-8970.

Sincerely,



Rose Allison, Senior Specialist
New Chemicals Notice Management Branch
Chemical Control Division (7405 M)